k132751

510(k) Summary
Multichem S Plus / S Plus (Assayed) Control

1.0 Submitter:

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2.0 Date Submitted:

August 28, 2013

OCT 2 2 2013

3.0 Device Identification

Proprietary Names:	Multichem S Plus / S Plus (Assayed)
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classification:	Class 1, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

4.0 Legally Marketed Predicate Device

Candidate(s)	Predicate	Manufacturer	Document Number
Multichem S Plus / S Plus (Assayed)	Liquid Assayed Multiqual® (Model #s 694, 695, 696, 695X)	Bio-Rad Laboratories	K043208

The Multichem S Plus / S Plus (Assayed) control is substantially equivalent to the Bio-Rad product listed above, currently in commercial distribution.

5.0 Device Description

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques and is an integral part of good laboratory practices. Three levels of control are available to allow performance monitoring within the analytical range. There is no difference in the formulation or manufacturing procedure between Multichem S Plus and Multichem S Plus (Assayed). Both are multi-analyte assayed QC materials with the same formula; however, there is a difference only in the product claims that are published to the users.

The following kit configurations are available:

Multichem S Plus (Assayed)
Model 05P78-10 with Level 1 control; 12 vials with 5 mL contents
Model 05P78-11 with Level 2 control; 12 vials with 5 mL contents
Model 05P78-12 with Level 3 control; 12 vials with 5 mL contents

Multichem S Plus
Model CH101PLA with Level 1 control; 15 vials with 10 mL contents
Model CH102PLA with Level 2 control; 15 vials with 10 mL contents
Model CH103PLA with Level 3 control; 15 vials with 10 mL contents

Each donor unit used in the preparation of the control material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and non-reactive for HBsAg.

6.0 Intended Use

Multichem S Plus / S Plus (Assayed) control are intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

Note: The following analytes are listed below in the table in section 7.0, in the package insert, and in the Indications for Use Form.

7.0 Comparison to the Predicate

Multichem S Plus / S Plus (Assayed) Plus control claims to be substantially equivalent to Liquid Assayed Multiqual®. The controls have same/similar design and modes of operation. The key features are summarized in the following table.

Characteristics	Predicate Device: Liquid Assayed Multiqual®	Proposed Device: Multichem S Plus / S Plus (Assayed) Controls
Similarities		
Intended Use:	Liquid Assayed Multiqual is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Multichem S Plus / S Plus (Assayed) control are intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form:	Liquid, Frozen	Liquid, Frozen
Matrix:	Human serum based	Human serum based
Storage (Closed/Shelf-Life)	-20°C to –70°C Until expiration date	-20° to -80°C Until expiration date

Differences			
Analytes	**Multiqual®**	**Multichem S Plus**	**Multichem S Plus (Assayed)**
	Acetaminophen	Acetaminophen	Acetaminophen
		Alpha-1 Acidglycoprotein	Alpha-1 Acidglycoprotein
	Alpha-1-Antitripsin	Alpha-1 Antitrypsin	Alpha-1 Antitrypsin
	αHBDH		
	Apolipoprotein A-1	Apolipoprotein A1	Apolipoprotein A1
	Apolipoprotein B	Apolipoprotein B	Apolipoprotein B
	Alkaline Phosphatase (ALP)	Alkaline Phosphatase	Alkaline Phosphatase
	ALT/SGPT	Alanine Aminotransferase	Alanine Aminotransferase
	Amikacin	Amikacin	Amikacin
	Amylase	Amylase	Amylase
	Amylase, Pancreatic	Amylase, Pancreatic	
	AST/SGOT	Aspartate Aminotransferase	Aspartate Aminotransferase
	Acid Phosphatase	Acid Phosphatase	
	Albumin	Albumin	Albumin
		Beta-2 Microglobulin	Beta-2 Microglobulin
		Bile acids	
	Bilirubin, Direct	Bilirubin, Direct	Bilirubin, Direct
	Bilirubin, Neonatal		
	Bilirubin, Total	Bilirubin, Total	Bilirubin, Total
	C3 Complement	Complement C3	Complement C3
	C4 Complement	Complement C4	Complement C4
	Ceruloplasmin	Ceruloplasmin	Ceruloplasmin
	Cholinesterase	Cholinesterase	
	Calcium, Ionized		
	Copper		
	Calcium, Total	Calcium	Calcium
	Carbamazepine	Carbamazepine	Carbamazepine
	Carbon Dioxide (CO2)	Carbon Dioxide (Bicarbonate)	Carbon Dioxide (Bicarbonate)
	Chloride	Chloride	Chloride
	HDL	Cholesterol, HDL	Cholesterol, HDL
	LDL	Cholesterol, LDL	Cholesterol, LDL
	Cholesterol, Total	Cholesterol, Total	Cholesterol, Total
	CK-MB Isoenzyme		
	Cortisol	Cortisol	
	Creatinine	Creatinine	Creatinine
	Creatine Kinase (CK)	Creatine Kinase	Creatine Kinase
		C-Reactive Protein	C-Reactive Protein
	Digoxin	Digoxin	Digoxin
	Ferritin		
	Ethanol	Ethanol	Ethanol

	GGT	Gamma Glutamyltransferase	Gamma Glutamyltransferase
	Gentamicin	Gentamicin	Gentamicin
	Globulin		
	Glucose	Glucose	Glucose
	Haptoglobin	Haptoglobin	Haptoglobin
	Iron	Iron	Iron
	Immunoglobulin A (IgA)	Immunoglobulin A	Immunoglobulin A
	Immunoglobulin G (IgG)	Immunoglobulin G	Immunoglobulin G
	Immunoglobulin M (IgM)	Immunoglobulin M	Immunoglobulin M
	TIBC		
	UIBC	Unsaturated Iron Binding Capacity (UIBC)	Unsaturated Iron Binding Capacity (UIBC)
	Lactate (Lactic Acid)	Lactate (Lactic acid)	Lactate (Lactic acid)
	LDH	Lactate Dehydrogenase	Lactate Dehydrogenase
	LAP Arylamidase		
	Lipase	Lipase	Lipase
	Lithium	Lithium	Lithium
	Magnesium	Magnesium	Magnesium
	Osmolality		
	Phenobarbital	Phenobarbital	Phenobarbital
	Phenytoin	Phenytoin	
	Phospholipids		
	Phosphorus	Phosphorous	Phosphorous
	Potassium	Potassium	Potassium
	Prealbumin	Prealbumin	Prealbumin
	PAP		
	Protein Electrophoresis		
	Protein, Total	Protein, Total	Protein, Total
		Rheumatoid Factor	Rheumatoid Factor
	Salicylate	Salicylate	Salicylate
	Sodium	Sodium	Sodium
	T3 Free		
	T3 Total		
	T3 Uptake/T-Uptake		
	T4 total	Thyroxine (TT4)	
	T4 Free		
	Theophylline	Theophylline	Theophylline
	TSH		
	Tobramycin	Tobramycin	Tobramycin
	Transferrin	Transferrin	Transferrin
	Triglycerides	Triglycerides	Triglycerides
	Urea		
	Urea Nitrogen (BUN)	Urea Nitrogen	Urea Nitrogen
	Uric Acid	Uric Acid	Uric Acid
	Valproic Acid	Valproic Acid	Valproic Acid

	Vitamin B12 Zinc	Vancomycin	Vancomycin
Open Vial	14 days at 2 to 8°C, with the following exception: Direct Bilirubin, Triglycerides, HDL, Cholinesterase and Phosphorus for 7 days. LAP Arylamidase will be stable for 3 days.	10 days at 2 to 8°C with the following exceptions: Triglycerides will be stable for 7 days. Lactate will be stable for 5 days.	

8.0 Performance Characteristics

8.1 Value Assignment Summary

Value assignment testing was performed utilizing internal procedures and protocols to determine typical values that would be seen for the controls across Abbott ARCHITECT c8000 clinical chemistry and the ARCHITECT i2000 immunoassay systems with the associated reagent test systems. For the Multichem S Plus / S Plus (Assayed) controls, 2 reagent lots and 2 calibrator lots were used where available to incorporate reagent and calibrator variation. 2 replicates from 16 runs were performed to give a total of 32 data points. Distinct runs, with minimum gaps of 2 hours were performed and a minimum of 8 calibration events were performed to incorporate variation from calibration and environmental sources. Value assignment ranges were established at the pre-determined criteria of 20% around the grand mean and expanded to 30% or as needed. However, a 10% range is applied to Potassium, Sodium and Chloride.

8.2 Stability Testing Summary

Stability studies have been performed to determine the open vial stability and shelf-life for this control. For open vial stability, Technopath utilized internal procedures and two protocol methods (Classical [Forward] method and Isochronous - Staggered Start [Backwards / Back-ended] method) from CLSI EP25A entitled "Evaluation of Stability of *In Vitro* Diagnostic Reagents." To minimize variation, where possible, one lot of reagent, calibrator and reference/control was used for the entire study, per analyte. Testing was performed over multiple days on 1 Abbott ARCHITECT c8000 clinical chemistry system with the associated reagent test systems, with the exception of Rheumatoid Factor, which was tested on a Beckman Coulter® AU480 chemistry instrument. All Multichem S Plus / S Plus (Assayed) analytes from open vial and freshly thawed vial samples were tested in replicates of 3 at each time point. Multiple time points were tested and the point of failure was determined by the maximum allowable drift (degradation), which was determined to be analyte specific.

Open Vial Stability:

- 10 days at 2 to 8°C for each analyte with the following exceptions:
  - 7 days at 2 to 8°C for Triglycerides
  - 5 days at 2 to 8°C for Lactate

A combination of accelerated and preliminary real-time testing was carried out utilizing CLSI EP25A in order to support a shelf-life storage claim of -20° to -80°C for 30 months. The accelerated testing utilized three lots of controls and the real-time testing utilized a combination of two lots of controls. All data was generated using the Abbott ARCHITECT c8000 clinical chemistry system with the associated reagent test systems. For the Multichem S Plus / S Plus (Assayed) controls, the Drift Limit was determined to be 10%. These results concluded that the Multichem S Plus / S Plus (Assayed) controls are predicted to be stable for in excess of 30 months when stored at -20°C to - 80°C. The real-time testing is on-going.

Note: ARCHITECT, c8000, and i2000 are trademarks of Abbott Laboratories.

8.3 Traceability Summary

The analytes contained within the Multichem S Plus / S Plus (Assayed) controls were obtained from endogenous components to the base serum matrix and commercially available sources. Technopath does not claim traceability to higher order reference materials or methods.

9.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the Multichem S Plus / S Plus (Assayed) control is as safe, as effective, and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2013

TECHNO-PATH MANUFACTURING LTD.
c/o Stephanie G. Garth
Global Compliance Plus
325 Big Elm Street
HIGHLAND VILLAGE TX 75077

Re: K132751
Trade/Device Name: Multichem S Plus / S Plus (assayed)
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJY
Dated: August 28, 2013
Received: September 3, 2013

Dear Ms. Garth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol E. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k132751

Device Name: Multichem S Plus / S Plus (Assayed)

Indications for Use:

Multichem S Plus / S Plus (Assayed) control are intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. Note: The following analytes are listed in the package insert:

Multichem S Plus

Acetaminophen
Alpha-1 Acidglycoprotein
Alpha-1 Antitrypsin
Apolipoprotein A1
Apolipoprotein B
Alkaline Phosphatase
Alanine Aminotransferase
Amikacin
Amylase
Amylase, Pancreatic
Aspartate Aminotransferase
Acid Phosphatase
Albumin
Beta-2 Microglobulin
Bile acids
Bilirubin, Direct
Bilirubin, Total
Complement C3
Complement C4
Ceruloplasmin
Cholinesterase
Calcium

Multichem S Plus (Assayed)

Acetaminophen
Alpha-1 Acidglycoprotein
Alpha-1 Antitrypsin
Apolipoprotein A1
Apolipoprotein B
Alkaline Alanine Aminotransferase
Amikacin
Amylase
Aspartate Aminotransferase
Albumin
Beta-2 Microglobulin
Bilirubin, Direct
Bilirubin, Total
Complement C3
Complement C4
Ceruloplasmin
Calcium
Carbamazepine
Carbon Dioxide (Bicarbonate)
Chloride

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132751

Multichem S Plus, cont'd

Carbamazepine
Carbon Dioxide (Bicarbonate)
Chloride
Cholesterol, HDL
Cholesterol, LDL
Cholesterol, Total
Cortisol
Creatinine
Creatine Kinase
C-Reactive Protein
Digoxin
Ethanol
Gamma Glutamyltransferase
Gentamicin
Glucose
Haptoglobin
Iron
Immunoglobulin A
Immunoglobulin G
Immunoglobulin M
Unsaturated Iron Binding Capacity (UIBC)
Lactate (Lactic acid)
Lactate Dehydrogenase
Lipase
Lithium
Magnesium
Phenobarbital
Phenytoin
Phosphorous
Potassium
Prealbumin
Protein, Total
Rheumatoid Factor
Salicylate
Sodium
Thyroxine (TT4)
Theophylline
Tobramycin
Transferrin
Triglycerides
Urea Nitrogen
Uric Acid
Valproic Acid
Vancomycin

Multichem S Plus (Assayed), cont'd

Cholesterol, HDL
Cholesterol, LDL
Cholesterol, Total
Creatinine
Creatine Kinase
C-Reactive Protein
Digoxin
Ethanol
Gamma Glutamyltransferase
Gentamicin
Glucose
Haptoglobin
Iron
Immunoglobulin A
Immunoglobulin G
Immunoglobulin M
Unsaturated Iron Binding Capacity (UIBC)
Lactate (Lactic acid)
Lactate Dehydrogenase
Lipase
Lithium
Magnesium
Phenobarbital
Phosphorous
Potassium
Prealbumin
Protein, Total
Rheumatoid Factor
Salicylate
Sodium
Theophylline
Tobramycin
Transferrin
Triglycerides
Urea Nitrogen
Uric Acid
Valproic Acid
Vancomycin

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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